REMARKS

This paper is responsive to the Office Action mailed May 7, 2007. Presently, claims 29-32, 34-36, 38, 41-46, 48 and 50-51 stand rejected. Claims 33, 37, 39, 40, 47, 49, 52 and 53 were objected to as being dependent upon a rejected base claim, but were indicated as being allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. Claims 1-28 have been withdrawn.

Generally speaking, the claims of the present application are directed to a radially expandable introducer sheath. Among other benefits, the use of the inventive radially expandable introducer sheath enables the medical professional to minimize the use of axial force when inserting a medical instrument through a dilated opening in the patient's body.

Although the axial insertion of medical instruments through a dilated opening in a patient's body is often accomplished in relatively straightforward fashion, in some instances, such as during a tracheostomy procedure, the medical professional may encounter difficulties when attempting such insertions. In these instances, the insertion force causes an undesired extension of the opening in the axial direction, and increases the trauma experienced by the patient at the site. For example, during a tracheostomy procedure, the dilator is advanced into the trachea through the dilated opening to open the trachea for introduction of a tracheostomy tube. The axial force exerted by the dilator may cause the trachea to collapse, thereby further increasing the trauma to the patient and preventing the establishment of proper ventilation. In order to minimize the possibility of a tracheal collapse, the physician must repeatedly insert and withdraw one or more dilators at incrementally greater distances and/or incrementally greater diameters until the desired dilated diameter is obtained. This process can be very time-consuming at the very time that prompt action may be

critical to the patient's well-being. Such problems are addressed with the use of a radially expandable introducer according to the present invention.

Section 102 rejections.

(a) Claims 29-32, 34, 38, 46, 48, 50 and 51 were rejected under 35 U.S.C. §102(b) as being anticipated by Fogarty et al (USP 4,271,839). Claims 29 and 46 are independent claims, and the remaining claims subject to this rejection are dependent, directly or indirectly, from claim 29 or 46.

Fogarty is directed to a method and apparatus for dilating occluded blood vessels. A portion 20b of a balloon element 16b is initially inverted within the distal end of a catheter 14. In use, a flexible catheter 22 everts the folded balloon portion from the catheter distal end (Fig. 7). The balloon portion is thereafter extruded through and expanded within the occlusion 12 being treated (Fig. 8).

Claim 29, as amended herein, is directed to an introducer sheath for use in the percutaneous insertion of an article into a body opening. A sheath body is configured to have an axial opening therethrough for passage of the article into the body opening. The sheath body is selectively movable between a non-expanded condition and a radially expanded condition, and has a proximal portion and a distal portion. The proximal portion is disposed along a proximal length of the sheath body. The distal portion comprises a folded portion when the sheath is in the non-expanded condition, and an extended portion when the sheath is in the radially expanded condition. An insertion member is provided to hold the folded distal portion of the sheath body in the non-expanded condition.

Fogarty does not teach an introducer sheath suitable for use in the percutaneous insertion of an article into a body opening. Rather, as stated, the Fogarty device is structured for dilating occluded vessels. While the Fogarty device is capable of expanding radially to dilate the vessel, it is not configured to include an axial opening therethrough to enable passage of an article into a body opening.

Furthermore, as shown in Fig. 7, the Fogarty device does not have a proximal portion disposed along a proximal length of the sheath body. Rather, both the proximal portion and the distal portion of Fogarty are folded within the catheter 14.

Thus, for at least the foregoing reasons, claim 29, as amended, is not anticipated by Fogarty. Claims 30-32, 34 and 38 depend, directly or indirectly, from claim 29, and include all of its limitations, including the limitation of an axial opening for passage of the article to be introduced into the body, and the limitation of a proximal portion that extends along a proximal length of the sheath body and a distal folded portion. Thus, these claims are not anticipated for at least the same reasons that claim 29 is not anticipated.

Claim 46, as amended herein, is directed to an introducer sheath system for use in the percutaneous insertion of an article in a body opening. The introducer sheath system includes an introducer sheath comprising a sheath body and an insertion cannula. The sheath body has an axial opening therethrough for passage of the article, and is selectively movable between a non-expanded condition and a radially expanded condition. A distal end of the sheath body is foldable within an inner lumen of the insertion cannula when the sheath is in the non-expanded condition, and extendable beyond the insertion cannula to permit radial expansion of the sheath. A dilator is engaged with the introducer sheath for dilating the body opening. The dilator has a tapered tip extending distal of the sheath body.

As explained above with reference to claim 29, Fogarty does not include an axial opening therethrough for passage of an article into a body opening. Thus, Fogarty cannot anticipate claim 46. In addition, Fogarty does not include a dilator having a tapered tip extending distal of the sheath body. In the Office Action, the Examiner identified reference numerals "(32, 38)" as meeting the limitation of the dilator. Reference numeral 32 corresponds to a fluid reservoir and reference numeral 38 corresponds to a syringe. Even if such elements somehow meet the limitation of a dilator, to which Applicants respectfully disagree, neither these elements, nor any

other elements in Fogarty, meet the limitation of a dilator having a tapered tip extending distal of the sheath body of the radially expandable sheath, as now claimed.

Thus, for at least the foregoing reason, claim 46, as amended, is not anticipated by Fogarty. Claims 48, 50 and 51 depend, directly or indirectly, from claim 46, and include all of its limitations, including the limitation relating to the distal tip of the dilator as explained above. Thus, these claims are not anticipated for at least the same reasons that claim 46 is not anticipated.

(b) Claims 29, 30 and 31 were rejected under 35 U.S.C. §102(b) as being anticipated by Aboul-Hosn (USP 5,741,234).

Abour-Hosn is directed to a sealing conduit for use with a portal formed in the body of a patient to allow insertion therethrough of surgical, diagnostic and assistive instruments. The sealing conduit includes an elongated cylindrical member with a continuous central lumen. According to the Examiner, Aboul-Hosn discloses a sheath (sealing conduit 10) having a folded portion (24?) and an insertion member (24, 14).

As explained above, claim 29 is directed to an introducer sheath for use in the percutaneous insertion of an article into a body opening. A sheath body is configured to have an axial opening therethrough for passage of the article into the body opening. The sheath body is selectively movable between a non-expanded condition and a radially expanded condition, and has a proximal portion and a distal portion. The proximal portion is disposed along a proximal length of the sheath body. The distal portion comprises a folded portion when the sheath is in the non-expanded condition, and an extended portion when the sheath is in the radially expanded condition. An insertion member is provided to hold the folded distal portion of the sheath body in the non-expanded condition.

Among other things, the Aboul-Hosn device does not include a sheath body

having a proximal portion and a distal portion as claimed, wherein the sheath body is selectively movable between a non-expanded condition and a radially expanded condition. More particularly, Aboul-Hosn does not disclose a sheath wherein the proximal portion extends along a proximal length of a sheath body, and the distal portion comprises a folded portion when the sheath is in the non-expanded condition and an extended portion when the sheath is in the radially expanded condition.

Thus, for at least the foregoing reason, claim 29, as amended, is not anticipated by Aboul-Hosn. Claims 30 and 31 depend, directly or indirectly, from claim 29, and include all of its limitations. Therefore, these claims are not anticipated for at least the same reasons that claim 29 is not anticipated.

(c) Claims 41, 42 and 45 were rejected under 35 U.S.C. §102(b) as being anticipated by Heck (USP 6,083,207). Heck is directed to a partitioned hemostasis valve for use in combination with a (splittable) introducer sheath to minimize bleeding when a medical device is inserted into the body of a patient through the sheath.

Claim 41, as amended herein, is directed to an introducer sheath for use in the percutaneous insertion of an article in a body opening. The sheath includes a radially expandable sheath body that is alignable to provide an axial opening for passage of the article therethrough into the body opening. A handle comprising an axial opening aligned with the sheath body axial opening for passage of said article therethrough is engaged with the sheath body. The handle includes a perimetrical opening for removal of the sheath from the inserted article in the body opening.

The sheath 20 utilized with the Heck device is not radially expandable from a non-expanded condition to an expanded condition in the nature of the radially expandable sheath as now claimed. Rather, sheath 20 is a conventional splittable sheath. Splittable sheath 20 cannot be radially expanded without splitting the sheath, thereby destroying its functionality. Thus, for at least the foregoing reason, claim 41,

as amended, is not anticipated by Heck. Claims 42 and 45 depend, directly or indirectly, from claim 41, and include all of its limitations. Therefore, these claims are not anticipated for at least the same reasons that claim 41 is not anticipated.

In addition, claim 45 has been amended to specify that the sheath body has a distal end comprising a folded portion when the sheath is in a non-expanded condition, and an extended portion when the sheath is in a radially expanded condition. The Heck device includes no such feature, nor has the Examiner identified any structure that would meet this limitation. Thus, Applicants submit that claim 45 is not anticipated for this additional reason.

Sec. 103(a) rejections.

(a) Claims 43 and 44 were rejected under 35 U.S.C. §103(a) as being unpatentable over Heck in view of Osborne (USP 4,306,562).

Claims 43 and 44 depend from claim 41 and include all of its limitations, including the limitation of a radially expandable sheath body. Osborne was cited for teaching a composition for an introducer sheath, and not as teaching a radially expandable body. Therefore, claims 43 and 44 are allowable for at least the same reasons that claim 41 is allowable.

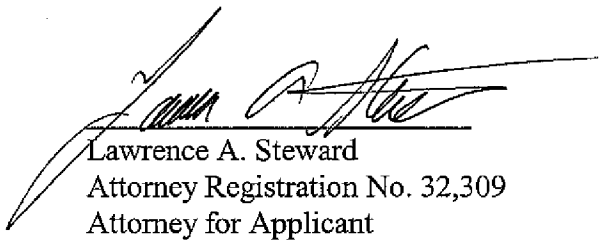
(b) Claims 35 and 36 were rejected under 35 U.S.C. §103(a) as being unpatentable over Fogarty et al in view of Osborne.

Claims 35 and 36 depend from claim 29 and include all of its limitations, including the limitation of an axial opening for passage of the article to be introduced into the body, and the limitation of a proximal portion disposed along a proximal length of the sheath body and a distal folded portion. Osborne was cited for teaching a composition for an introducer sheath. Therefore, claims 35 and 36 are allowable for at least the same reasons that claim 29 is allowable.

Conclusion:

Based upon the foregoing, Applicants respectfully submit that the grounds for rejection of claims 29-32, 34-36, 38, 41-46, 48 and 50-51 have been overcome, and that all claims 29-52 are in condition for allowance. If the Examiner believes that prosecution of this application may be advanced by way of a telephone conversation, the Examiner is respectfully invited to telephone the undersigned attorney.

Respectfully submitted,



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